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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/635,353	08/06/2003	Robert M. Danen	39032	8901	
3000	7590 07/05/2006		EXAMINER RAMIREZ, JOHN FERNANDO		
•	IVISE, BERNSTEIN,				
	LOOR, SEVEN PENN CENTER		ART UNIT	PAPER NUMBER	
1635 MARKET STREET			3737		
PHILADELPH	HIA, PA 19103-2212	•	DATE MAILED: 07/05/2000	DATE MAILED: 07/05/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Commence	10/635,353	DANEN, ROBERT M.				
Office Action Summary	Examiner	Art Unit				
	John F. Ramirez	3737				
- The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on						
	— s action is non-final.					
3) Since this application is in condition for allowa	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-6</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-6</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 01/06/05; 12/01/03.</li> </ol>	Paper No(s)/Mail Da  5) Notice of Informal Pa  6) Other:	atent Application (PTO-152)				

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites the limitation "the step of inputting" in first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Correction is required.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Groner et al. (US 6,104,939).

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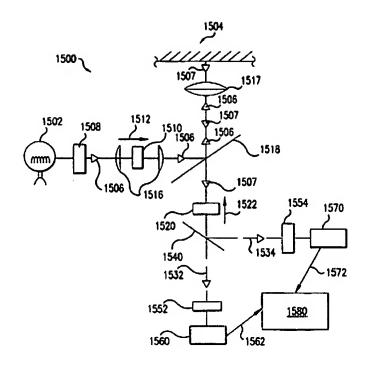


FIG.15B

The Groner et al. patent discloses a method for correcting light intensities from blood vessels and background tissue beneath tissue surface in a living being that are exposed to polarized light from an orthogonal polarized spectral (OPS) imaging system (see Fig. 15B, 1510, 1520), including the steps of: emitting polarized light at tissue comprising blood vessels and background tissue (see abstract, col. 4, line 51- col. 5, line 2), the blood vessels being located at a focal plane of the OPS imaging system and wherein a foreground region is formed between the focal plane and the tissue surface (col. 33, lines 30-38); collecting de-polarized light that has impacted the blood vessels and that has experienced scattering within the foreground region, the de-polarized light emerging from the tissue surface (col. 26, line 44 - col. 27, line 31); generating a first

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image based on the collected de-polarized light; estimating the intensity of light scattered in the foreground region; and subtracting the intensity of light scattered in the foreground region from the first image to generate a corrected image based on focal plane light intensities, inputting the scattered light intensities, the focal plane light intensities, the absorptivity of hemoglobin and the diameter of the blood vessels into Beer's Law to determine hemoglobin concentration (see Abstract).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groner et al. (US 6,104,939) in view of Block et al. (US 6,420,709).

With respect to claim 2, Groner et al. teaches all the limitations of the claimed subject matter except for mentioning specifically the steps of generating a probability function based on a photon of the depolarized light, centering the probability function along an axis within the focal plane and multiplying the probability function with the first image to form a light intensity of scattered light, and summing all of the scattered light intensities from the focal plane.

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However, the steps of estimating-the intensity of light scattered in the foreground region, generating a probability function based on a photon of the depolarized light, centering the probability function along an axis within the focal plane and multiplying the probability function with the first image to form a light intensity of scattered light, and summing all of the scattered light intensities from the focal plane are considered conventional in the art as evidenced by the teachings of Block et al. (US 6,420,709).

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The Block et al. reference discloses a method to calculate the probability of intensity of light scattered using a standard Monte Carlo computation.

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Groner et al., with the above discussed enhancements would have been considered obvious because such modifications would have improved visualization of the reflected image to determine characteristics such as the hemoglobin concentration in blood.

In relation to claims 4-6, Groner et al. discloses the claimed invention except for mentioning specifically the steps of claim 2, utilizing the following relationship:

$$I_s(x) = \int_{image} (dx_i)^2 P_s(|x - x_i|, z_f) \cdot I^M(x_i)$$

wherein

x = an axis within the focal plane:

 $I_n(x)$  = the light intensity of scattered light;

P<sub>s</sub> = probability function based on a photon of said de-polarized light originating from the focal plane at a location x<sub>i</sub> along said x axis; and

I<sup>M</sup>(x)= said collected de-polarized light that has impacted the blood vessels and that has experienced scattering within said foreground region and emerged from the tissue surface.

the step of subtracting the scattered light intensities from the first image to determine focal plane light intensities comprises utilizing the following relationship;

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$$I_f(x) = \frac{I^M(x) - I_s(x)}{\exp(-\mu_t z_f)}$$

wherein,

 $l_i(x) = focal_iQlane light intensities;$ 

 $\mu_i$  = is the thinsport coefficient of the foreground region; and

z<sub>4</sub> = the distance between said foreground region and the tissue surface.

and the step of determining the hemoglobin concentration in the blood vessel using the following relationship;

$$Hb = -\frac{1}{\alpha D} \log \left( \frac{I_f(x_*)}{I_f(x_b)} \right) = -\frac{1}{\alpha D} \log \left( \frac{I_f(x_*) - I_i(x_*)}{I''(x_b) - I_i(x_b)} \right)$$

wherein,

[Hb] = concentration of hemoglobin;

 $\alpha$  = absorptivity of hemoglobin;

D = diameter of the blood vessel

 $I_i(x_v)$  = focal plane light intensity evaluated at vessel x-axis position;

 $I_{n}(x_{n})$  = focal plane light intensities evaluated at background x-axis position;

 $I_{\epsilon}(x)$  = the light intensity of scattered light evaluated at vessel x-axis position;

 $I_s(x_b)$  = the light intensity of scattered light evaluated at background x-axis position;

f<sup>M</sup>(x<sub>v</sub>)= said collected de-polarized light that has impacted the blood vessels and that has experienced scattering within said foreground region and emerged from the tissue surface evaluated at vessel x-axls position; and

I<sup>M</sup>(x<sub>b</sub>)= said collected de-polarized light that has impacted the blood vessels and that has experienced scattering within said foreground region and emerged from the tissue surface evaluated at background x-axis position.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to enhance the capabilities of the device and method disclosed by Groner et al. to improve visualization of the reflected image to determine characteristics such as the hemoglobin concentration in blood, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JFR 06/16/06

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700